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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,508	09/12/2005	Jonathan Alexander Terrett	2543-1-038PCT/US	2562
23565 KLAUBER & J	7590 04/02/200° JACKSON		EXAMINER	
411 HACKENSACK AVENUE HACKENSACK, NJ 07601		,	HALVORSON, MARK	
			ART UNIT	PAPER NUMBER
			1642	
SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
31 DAYS		04/02/2007	PAPER	

## Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)			
Office Action Summary	10/510,508	TERRETT, JONATHAN ALEXANDER			
Office Action Summary	Examiner	Art Unit			
	Mark Halvorson	1642			
The MAILING DATE of this communication a Period for Reply	ppears on the cover sheet wi	th the correspondence address			
A SHORTENED STATUTORY PERIOD FOR REF WHICHEVER IS LONGER, FROM THE MAILING - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication If NO period for reply is specified above, the maximum statutory perions - Failure to reply within the set or extended period for reply will, by state that the period for reply will, by state that the material patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNIC 1.136(a). In no event, however, may a root od will apply and will expire SIX (6) MON tute, cause the application to become AB	CATION.  apply be timely filed  THS from the mailing date of this communication.  ANDONED (35 U.S.C. § 133).			
Status					
1) Responsive to communication(s) filed on <u>07</u>	January 2004.				
2a) ☐ This action is <b>FINAL</b> . 2b) ☐ The section is <b>FINAL</b> .	This action is <b>FINAL</b> . 2b) This action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice unde	r <i>Ex parte Quayle</i> , 1935 C.D	. 11, 453 O.G. 213.			
Disposition of Claims					
4) ☐ Claim(s) 1-11,16-23 and 25-27 is/are pending 4a) Of the above claim(s) is/are withd 5) ☐ Claim(s) is/are allowed.  6) ☐ Claim(s) is/are rejected.  7) ☐ Claim(s) is/are objected to.					
8) Claim(s) <u>1-11,16-23 and 25-27</u> are subject to	o restriction and/or election r	equirement.			
Application Papers	•				
9) The specification is objected to by the Exami 10) The drawing(s) filed on is/are: a) a Applicant may not request that any objection to the Replacement drawing sheet(s) including the correction.	ccepted or b) objected to be drawing(s) be held in abeyant ection is required if the drawing	ce. See 37 CFR 1.85(a). (s) is objected to. See 37 CFR 1.121(d).			
11) ☐ The oath or declaration is objected to by the	Examiner. Note the attached	TOTICE Action of form PTO-152.			
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign     a) All b) Some * c) None of:     1. Certified copies of the priority docume     2. Certified copies of the priority docume     3. Copies of the certified copies of the priority docume     application from the International Bure     * See the attached detailed Office action for a li	ents have been received. ents have been received in A riority documents have been eau (PCT Rule 17.2(a)).	pplication No received in this National Stage			
Attachment(s)  1) Notice of References Cited (PTO-892)		Summary (PTO-413)			
<ul> <li>2) Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3) Information Disclosure Statement(s) (PTO/SB/08)         Paper No(s)/Mail Date     </li> </ul>	5) 🔲 Notice of Ir	s)/Mail Date nformal Patent Application <u>uence search results</u> .			

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## **DETAILED ACTION**

Claims 1-11, 16-23, 25-27 are pending.

## Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-5, and 7 drawn to a method of screening for breast lung and pancreatic cancer comprising detecting an NKCCI polypeptide.

Group 2, claim(s) 1-5, and 7 drawn to a method of screening for breast lung and pancreatic cancer comprising detecting a nucleic acid molecule.

Group 3, claim(s) 1-5, and 7 drawn to a method of screening for breast lung and pancreatic cancer comprising detecting an NKCCI polypeptide and a nucleic acid molecule.

Group 4, claim(s) 6, 8 and 9 drawn to an antibody that specifically binds to a polypeptide.

Group 5, claim(s) 10, 16, and 17 drawn to a method for the prophylaxis and/or treatment of cancer comprising administering a polypeptide.

Group 6, claim(s) 10, 16, and 17 drawn to a method for the prophylaxis and/or treatment of cancer comprising administering a nucleic acid.

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Group 7, claim(s) 10, 16, and 17 drawn to a method for the prophylaxis and/or treatment of cancer comprising administering a polypeptide and a nucleic acid.

Group 8, claim(s) 11, drawn to a method for the prophylaxis and/or treatment of cancer comprising administering an antibody.

Group 9, claim(s) 18 and 19, drawn to a method of screening for agents that interact with a polypeptide.

Group 10, claim(s) 20-22, drawn to a method of screening for cancer agents that modulate the expression or activity of a polypeptide for further testing an anti-cancer agent.

Group 11, claim(s) 20-22, drawn to a method of screening for cancer agents that modulate the expression of a nucleic acid.

Group 12, claim(s) 23 and 25 drawn to an agent that binds a polypeptide and causes the expression or activity of that polypeptide to change.

Group 13, claim(s) 23 and 25 drawn to an agent that binds a polypeptide and causes the expression of a nucleic acid to change.

Group 14, claim(s) 26, drawn to a method for the prophylaxis and/or treatment of cancer comprising administering an active agent that interacts with a polypeptide which modulates the expression of the polypeptide.

Group 15, claim(s) 26, drawn to a method for the prophylaxis and/or treatment of cancer comprising administering an active agent that interacts with a polypeptide which modulates the expression of nucleic acid molecule.

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Group 16, claim(s) 27, drawn to an agent identified by a method of screening for cancer agents that modulate the expression of a polypeptide.

Group 17, claim(s) 27, drawn to an agent identified by a method of screening for cancer agents that modulate the expression of a nucleic acid.

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Unity of invention is fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding, special technical features which define a contribution over the prior art. If there is no special technical feature, if multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c), 37 C.F.R. 1.475(d)

The invention listed as Groups 1-9 do not relate to a single inventive concept under PCT Rule 1.31 because, under PCT 13.2 they lack the same or corresponding special technical feature for the following reasons:

The technical feature of claim 1 is a method of screening for breast, lung or pancreatic cancer comprising the step of detecting an NKCC1 polypeptide comprising the amino acid sequence of SEQ ID NO:1..

However, Veiby (U.S. Patent Application Publication No: 2003/0068636, published April 10, 2003, priority filing date June 27, 2001) describes a method for screening for a breast cancer comprising detecting a polypeptide that is identical to the polypeptide of SEQ ID NO:1 of the instant application (paragraph 119-121, sequence search results). Thus, Claim 1 lacks the special technical feature.

Thus, the different groups in the present application do not contain a single inventive concept and puts a serious search burden on the Examiner.

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The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from

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8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley, can be reached at (571) 272-0898. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Halvorson, PhD Patent Examiner 571-272-6539

> MISOOK YU SEIMARY EXAMINER

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<!--StartFragment-->RESULT 1
US-10-176-847-74
; Sequence 74, Application US/10176847
 Publication No. US20030068636A1
 GENERAL INFORMATION:
  APPLICANT: Veiby, Petter Ole
  TITLE OF INVENTION: COMPOSITIONS, KITS, AND METHODS FOR
  TITLE OF INVENTION: IDENTIFICATION, ASSESSMENT, PREVENTION, AND THERAPY OF BREAST
  TITLE OF INVENTION: AND OVARIAN CANCER
  FILE REFERENCE: MRI-039
  CURRENT APPLICATION NUMBER: US/10/176,847
  CURRENT FILING DATE: 2002-06-21
  NUMBER OF SEQ ID NOS: 112
  SOFTWARE: FastSEQ for Windows Version 4.0
; SEQ ID NO 74
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